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K -011898

510(k) Summary

1. **Name/Address of Submitter:** **e-Med Innovations, Inc.**
5001 LBJ Freeway, Suite 930A
Dallas, Texas 75244

2. **Contact Person:** **Pierre Laute**
Vice President Engineering
(469) 374-0123

3. **Date Summary Prepared: June 11, 2001**

4. **Device Name: E-Steth Electronic Stethoscope**

5. **Predicate Devices:** **Meditron Electronic Stethoscope,**
3M Littman Electronic Stethoscope

6. **Device Description and Intended Use:**

The E-Steth Electronic Stethoscope is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies, records, stores, plays back, and transmits sounds associated with the heart and other internal organs. Significant components include a control unit, installation software; earphones, and communication cable. The E-Steth amplifies sounds in a broad frequency range, including a range higher than the traditional diaphragm mode. The user must supply a personal computer with a Microsoft Windows 95/98 or NT 4.0 operating system, a sound card, and CD-ROM drive. The stored sounds can be transmitted via e-mail. This device is a stand-alone unit, has no software and operates using an analog system with a standard earpiece. It can be converted to electronic by the user buying and using a sound card. The E-Steth records the heartbeat as a stand-alone device. It can be connected to a computer to record information, but the software does not operate the stethoscope in any manner."

7. **Brief Description of Nonclinical Testing:**

The specifications for the environmental and electromagnetic compatibility (EMC) testing of the E-Steth reference appropriate voluntary standards. All products specifications were met.

8. **Brief Description of Clinical Testing:**

Clinical study information was not submitted for the purpose of demonstrating substantial equivalence to legally marketed electronic stethoscopes. The product was tested and certified by France and the European Union. See Exhibits A, B and C.

9. Conclusions Drawn:

The indications for use are consistent with those for legally marketed electronic stethoscopes. Differences in technological characteristics from those of the cited predicate devices do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

e-Med Innovations, Inc.
c/o Mr. Hugh E. Hackney
Locke Liddell & Sapp LLP
2200 Ross Avenue, Suite 2200
Dallas, TX 75201-6776

Re: K011898
Trade Name: E-Steth Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: June 14, 2001
Received: June 18, 2001

Dear Mr. Hackney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011898

INDICATIONS FOR USE

"The E-Steth Electronic Stethoscope is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies, records, stores, plays back, and transmits sounds associated with the heart and other internal organs. Significant components include a control unit, installation software earphones, and a communication cable. The E-Steth amplifies sounds in a broad frequency range, including a range higher than the traditional diaphragm mode. The user must supply a personal computer with a Microsoft Windows 95/98 or NT 4.0 operating system, a sound card, and CD-ROM drive. The stored sounds can be transmitted via e-mail. This device is a stand-alone unit, has no software and operates using an analog system with a standard earpiece. It can be converted to electronic by the user buying and using a sound card. The E-Steth records the heartbeat as a stand-alone device. It can be connected to a computer to record information, but the software does not operate the stethoscope in any manner."

Division of Cardiovascular & Respiratory Devices
510(k) Number K011898

Prescription Use ✓